indirect pairwise odds ratios (OR) were obtained. The study used Bayesian Analysis Using Gibbs Sampling in Windows (WinBUGS) version 1.4.3. and Monte Carlo Simulations to conduct a multiple treatment comparison. Results are reported in OR with 95% credible intervals (CI) and the median of ranking. **RESULTS:** There were a total of 10 studies with 23 treatment arms, representing 2,885 subjects enrolled, that were included in the analysis. The results from fix effects model indicated that duloxetine, pregabalin, gabapentin, and co-administration of duloxetine and gabapentin were significantly better than amitriptyline (OR= 3.22[95%CI, 1.54-7.17], OR = 2.53[95%CI, 1.11-5.94], OR = 4.00[95%CI, 1.33-11.69], OR = 2.86[95%CI, 1.09-7.48], respectively). The results from random effects model suggested that only duloxetine and pregabalin were significantly better than placebo (OR = 2.61[95%CI, 1.37-4.95] and OR = 1.97[95%CI, 1.01-3.62], respectively). There was no significant difference between amitriptyline and placebo in either fixed or random effects models. With regard to the median ranking, gabapentin was ranked first, followed by duloxetine, co-administration of duloxetine and gabapentin, pregabalin, placebo, and amitriptyline from the fix effects model. **CONCLUSIONS:** Treatment of PDPN with amitriptyline does not appear to be significantly different from placebo. Duloxetine and pregabalin appear to be better than both amitriptyline and placebo.

PDB11

RESULTS OF GALATA STUDY: GALVUS EFFICACY AND SAFETY ASSESSMENT IN TURKISH POPULATION

Keskin L[1], Dokmetas HS[2], Akin F[3], Ayvaz G[4], Boz M[5], Canberk A[6], Tasan E[7], Guler S[8], Delibasi T[9], Sahin M[10], Uren E[11]

[1]*Malatya State Hospital, Malatya, Turkey,* [2]*Cumhuriyet University School of Medicine, Sivas, Turkey,* [3]*Pamukkale University School of Medicine, Denizli, Turkey,* [4]*Gazi University School of Medicine, Ankara, Turkmenistan,* [5]*Istanbul Training and Research Hospital, Istanbul, Turkey,* [6]*Istanbul University, Istanbul School of Medicine, Istanbul, Turkey,* [7]*Bezmialem Foundation University Hospital, Istanbul, Turkey,* [8]*Numune Training and Research Hospital, Ankara, Turkey,* [9]*Diskapi Training and Research Hospital, Ankara, Turkey,* [10]*Ankara University School of Medicine, Ankara, Turkey,* [11]*Novartis Pharma AG, Istanbul, Turkey*

OBJECTIVES: The GALATA study was the first observational study on DPP-4 inhibitors in Turkey and aimed to evaluate the efficacy, safety and tolerability of vildagliptin and metformin combination (VMc) in patients with type 2 diabetes mellitus (T2DM). **METHODS:** A total of 648 of the 682 screened T2DM outpatients (age >18 years) on VMc for at least 4 weeks prior to enrollment were included in this 24-week, multicenter, observational study. **RESULTS:** Of the 648 patients, 382 (59.0%) were female. The mean (standard deviation-SD-) age was 55.2 (10.2) years, the mean (SD) T2DM duration was 4.8 (5.2) years and 220 (34.0%) patients had T2DM for more than 5 years. Patients were followed for median (inter-quartile range-IQR-) 184.0 (74.0) days at median (IQR) 4.0 (2.0) visits. Median vildagliptin and metformin doses were 100.0 mg and 2000 mg, respectively. HbA1c decreased from 7.8% to 7.0% (p<0.001). A similar reduction in HbA1c from 7.6% to 7.1% was also seen in elderly patients (>65 years, 18.1% of patients) (p<0.001). The proportion of patients with HbA1c ≤6.5% increased from 13.3% to 42.7% (p<0.001) and those with HbA1c ≤7.0% increased from 26.6% to 65.3% (p<0.001). Mean fasting plasma glucose (FPG) decreased from 153.1 mg/dL to 136.5 mg/dL (p<0.001), whereas mean post-prandial plasma glucose (PPG) decreased from 217.6 mg/dL to 182.1 mg/dL (p<0.001). Eighty (12.3%) patients experienced 122 adverse events (AEs) including 3 serious AEs; 2 SAEs were not suspected to be related to VMc. AEs were mostly (94.3%) mild or moderate in severity and no action was taken for 44.3% of them; 76.2% of AEs resolved during follow-up. **CONCLUSIONS:** The results of the GALATA study suggested that VMc significantly decreased HbA1c, FPG and PPG, achieved glycemic control targets even in elderly patients and demonstrated good overall safety and tolerability in T2DM patients.

PDB12

EFFICACY AND SAFETY OF TREATMENTS OF TYPE 2 DIABETES MELLITUS (T2DM): A SYSTEMATIC REVIEW (SLR)

Pettré S[1], Selya-Hammer C[1], Ho S[1], Garg M[2], Schroeder M[3], Kaur V[4], Hemels M[2]

[1]*Amaris, London, UK,* [2]*Janssen Cilag, Birkerød, Denmark,* [3]*Janssen UK, High Wycombe, UK,* [4]*Consultant, Mumbai, India*

OBJECTIVES: Collect randomized clinical evidence on the efficacy and safety of antidiabetic agents used in dual or triple therapy or add-on to insulin to provide a qualitative overview of the available evidence and undertake a meta-analysis. **METHODS:** A SLR was conducted in line with NICE guidelines to identify randomised controlled trials assessing agents received in combination with metformin (MET), a sulphonylurea (SU), MET+SU, MET+pioglitazone, or insulin. Interventions of interest included SGLT-2 inhibitors (canagliflozin and dapagliflozin), sulphonylureas, pioglitazone, DDP-4 inhibitors, GLP-1 analogues and insulin. Electronic searches were undertaken using Medline, Medline-in-process, Embase, and the Cochrane Library and supplemented with hand searches. An ad hoc search was conducted to identify the most recent data at 104 weeks. **RESULTS:** A total of 159 clinical trials met inclusion criteria. The frequency of studies by background therapy was as follows: MET (38%), mixed (trials containing treatment arms with different background therapies; 25%), insulin (21%), MET+SU (9%), and SU alone (8%). One study (assessing canagliflozin) featured a background of MET+pioglitazone. Studies varied in terms of treatment duration (12 to 104 weeks), presence and duration of run-in periods (57% studies with run-in, from 0.7 to 18 weeks), HbA1c eligibility criteria (minimum from 6% to 7%), body mass index (BMI; 37 studies focused on overweight and obese patients, two studies focused on obese patients) and age for inclusion (from ≥18 to ≤ 85 years). **CONCLUSIONS:** The outcome of this SLR will serve as input-data in a meta-analysis, to assess relative efficacy of T2DM treatments in different background therapy settings.

PDB13

RESULTS OF THE POST-MARKETING SURVEY OF VILDAGLIPTIN IN FRANCE

Eschwège E[1], Attali C[2], Bringer J[3], Simon D[4], Bouee S[5], Kind B[6], Quere S[7], Dejager S[7], Detournay B[5]

[1]*INSERM, Villejuif, France,* [2]*Cabinet Médical de Groupe, Epinay sous sénart, France,* [3]*CHRU Montpellier, Montpellier, France,* [4]*Hôpital de la Pitié, Paris, France,* [5]*Cemka, Bourg la Reine, France,* [6]*Novartis, Rueil-Malmaison, France,* [7]*Novartis Pharma, Rueil Malmaison, France*

OBJECTIVES: To assess the effectiveness, tolerability and maintenance of vildagliptin in type 2 diabetes (T2D) patients under real-life conditions in France, requested by the French Health Technology Agency. **METHODS:** A representative sample of T2D patients initiating a treatment with vildagliptin was enrolled in a 2 years follow-up observational cohort in 2010 by a national sample of endocrinologists and general practitioners. **RESULTS:** A total of 482 GPs and 84 endocrinologists included 1,700 patients. 60% were males, mean age=63 (±9) years, mean disease duration=7 (±6.5) years. Follow up visits were available for 96.3%, 90.7%, 86.5% and 81.8% of patients at respectively 6, 12 18 and 24 months. Mean HbA1c level decreased from 7.8% (sd=1.3) before vildagliptin prescription to 7.0% (sd=1.0) 0 to 6 months after vildagliptin initiation and remained stable thereafter: 7.0% (sd=1.0), 7.0% (sd=0.9) and 7.0% (sd=1.0) 6 to 12 months, 12 to 18 months and 18 to 24 months after vildagliptin initiation. The percentages of patients with alanine and/or aspartate aminotransferase above 120 UI were 0.5% before vildagliptin prescription and 0.3%, 0.5%, 0.1%, 0.0% at 0-6 months, 6-12 months, 12-18 months and 18-24 months after vildagliptin prescription. The mean glomerular filtration rate (MDRD formula) was 82.0 ml/minute before vildagliptin prescription and 82.4, 84.1, and 83.6 and 82.8, at 0-6 months, 6-12 months, 12-18 months and 18-24 months after vildagliptin prescription. The incidence of severe hypoglycemia (requiring third party assistance) has been estimated at 0.30/100 vildagliptin treated patients years (CI95%=[0.15,0.55]). All occurred in patients also treated with insulin and/or sulfamide The proportion of patients treated with vildagliptin remained high over the course of the study: 96.5% (CI95%[95.6,97.4]) after 6 months, 92.5% (CI95%=[91.2%,93.8%]) after one year and 88.8% (CI95%=[87.2%,90.4%]) after 2 years. **CONCLUSIONS:** Vildagliptin showed sustained effectiveness in terms of reduction in HbA1c over 24 months, with a low incidence of hypoglycemia.

PDB14

CLINICAL OUTCOMES AND HEALTH CARE COSTS EVALUATION OF SULFONAMIDES AND THIAZOLIDINEDIONES COMPARED WITH DIPEPTIDYL PEPTIDASE 4 INHIBITORS FOR THE TREATMENT OF UNCONTROLLED DIABETES

Degli Esposti L, Saragoni S, Buda S, Degli Esposti E

CliCon Srl, Ravenna, Italy

OBJECTIVES: To compare clinical outcomes and the health care costs across two cohorts of uncontrolled diabetic patients who initiated treatment with Sulfonamides or Thiazolidinediones (SU/TZD) or Dipeptidyl Peptidase 4 (DPP-4) Inhibitors in a clinical practice setting. **METHODS:** A retrospective analysis using a large administrative database and a clinical registry containing laboratory results of three Italian Local Health Units was performed. The index-period ranged from July, 2008 and June, 2010. Patients were treatment naïve to SU/TZD or to DPP-4, but already treated with other oral antidiabetic agents. Demographics, concomitant therapies, Charlson comorbidity index, glycemic and lipid control level and previous hospitalizations were assessed at baseline. Adherence was measured by *Medication Possession Ratio* (MPR). We calculated unadjusted rates and used a Poisson regression model to estimate risk ratios for diabetes-related hospitalizations occurred during the 18-months follow-up period. Total annual costs included all the pharmacological treatments and the direct costs due to hospitalizations and outpatient services. **RESULTS:** We identified 1384 patients treated with SU/TZD and 199 treated with DPP-4. DPP-4 patients were significantly younger (mean age 59.2 years and 65.0 years; p<0.001) and with less previous hospital discharges for diabetes-related diseases. Baseline mean HbA1c was 8.1% for SU/TZD and 8.2% for DPP-4 patients. DPP-4 naïve resulted more adherent (MPR≥80%) than SU/TZD naïve (70.9% and 55.8%; p<0.001). The SU/TZD group showed a significant increased risk of diabetes-related hospitalizations (unadjusted rate was 9,17 vs 3,47 per 100 person-years, p=0.002; adjusted incidence rate ratio 1.83; p=0.028). The higher hospitalization rate resulted in higher total annual direct costs per patient (€2.719 vs €2.462 of those treated with DPP-4). **CONCLUSIONS:** Results indicate that uncontrolled diabetic patients who initiated treatment with DPP-4, compared with those initiating with SU/TZD, are associated with a reduced risk of diabetes-related hospitalizations and consequently with a lower overall total annual cost per patient.

PDB15

THE PRESENCE OF METABOLIC AND OTHER RISK FACTORS IN ADRENAL INSUFFICIENCY PATIENTS COMPARED TO AN UNMATCHED BACKGROUND POPULATION FROM THE SAME REGION IN THE UNITED KINGDOM

Teneishvili M[1], Marelli C[2], Lee D[3]

[1]*ViroPharma LTD., Maidenhead, UK,* [2]*ViroPharma SPRL, Maidenhead, UK,* [3]*BresMed, Sheffield, UK*

OBJECTIVES: To describe epidemiological characteristics among adrenal insufficiency (AI) patients and describe the prevalence of risk factors in primary and secondary AI (PAI; SAI) and an unmatched, non-AI population. These analyses explore metabolic morbidity in AI, which literature suggests may be associated to a non-physiological cortisol profile. **METHODS:** Initial aggregated data from the FARSITE database were analysed. The prevalence of risk factors was evaluated, including hypertension, BMI, diabetes and depression, and compared across PAI, SAI and non-AI populations. Characteristics of non-AI patients were not matched with AI patients. **RESULTS:** A total of 261,638 patients were included; 62 PAI and 191 SAI. Prevalence of hypertension was 32% in PAI, 22% in SAI and 13% non-AI. 26% of hypertension in SAI was not on target according to QOF criteria (14% non-AI; 10% PAI). Hypercholesterolemia occurred in 13% of PAI and 6% of SAI patients (3% non-AI). Among SAI patients, 69% were overweight (BMI>25) or obese (BMI>30) (63% PAI; 39% non-AI). Diabetes (Type 1 and 2) was prevalent in 13% of PAI and 10% of SAI (5% non-AI), with HbA1c not controlled according to QOF criteria in 75% of PAI and 74% of SAI patients. Psychological risk factors were more prevalent among AI patients; 24% of PAI and 14% of SAI patients recently received anti-anxiety/depression treatment (6% non-AI). Hypnotics were recently prescribed to 6% of SAI patients (1% non-AI; PAI not reported). Bisphosphonates are used by 21% of PAI and 8% of SAI patients (2% non-AI). The hospital admission rate was 3% for SAI patients (1% non-AI; PAI not reported). **CONCLUSIONS:** The prevalence of metabolic and other risk factors is considerably higher among AI patients